K123436

AUG 26 2013

510(k) SUMMARY

Submitted by:	Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543
Contact Person:	Joseph Ciccone, Senior Manager, Regulatory Affairs
Date Prepared:	August 26, 2013
Proprietary Name:	FIRST RESPONSE™ Early Result Pregnancy Test
Common Name:	At-home Pregnancy Test
Classification Name:	Human chorionic gonadotropin (hCG) test system [21 CFR §862.1155] 75 LCX; Class II
Predicate Device:	FIRST RESPONSE™ Early Result Pregnancy Test 510(k) #K083716

Description of Device: The FIRST RESPONSE™ Early Result Pregnancy Test is a test system for the detection of human chorionic gonadotropin (hCG) hormone. Specifically, it is a screening device intended for the early detection of pregnancy by the lay user through the qualitative detection of hCG in urine, in some cases as early as six (6) days before the day of the missed period. The device detects the presence of hCG in the urine of a pregnant woman by way of a series of immunochemical reactions via component reagents that are striped onto a chromatographic strip contained within a plastic housing. Following the instructions for use provided with the device, the test is performed by placing the absorbent pad of the device into the urine stream for 5 seconds (or alternatively by fully immersing the absorbent pad for 5 seconds in a urine sample that was collected in a cup). The test result is displayed at the housing window for reading by the layer user after the elapse of 3 minutes. Two pink lines indicate that hCG has been detected (pregnant); one pink line indicates that no hCG has been detected (not pregnant).

Intended Use of the Device: The FIRST RESPONSE™ Early Result Pregnancy Test is an over-the-counter chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.

All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

Technological Characteristics: The 510(k)-subject FIRST RESPONSE™ Early Pregnancy Test does not represent a change in fundamental technology from the predicate FIRST RESPONSE™ Early Result Pregnancy Test device (510(k) K083716), only modifications

thereto. They are substantially equivalent. Both devices utilize the identical immunochemical principles for the detection of hCG. They differ in that the 510(k)–subject device has been modified to include an additional monoclonal antibody capable of detecting hCG beta core fragment (hCG βcf). hCG βcf is produced in early pregnancy (1) and its detection is intended to improve the clinical performance of the device. Detection of hCG βcf also prevents or reduces the potential for a false negative test result because hCG βcf is the major form of immunoreactive urinary hCG commonly found in later pregnancy (2, 3).

A number of laboratory and consumer use studies were undertaken to demonstrate that the 510K-subject device is substantially equivalent to the predicate device for the detection of pregnancy as early as 6 days before the day of missed period. These studies are as follows:

- A laboratory study to demonstrate the accuracy of the 510(k)-subject device compared to the accuracy of the predicate device using urine samples quantified for hCG levels from pregnant and non-pregnant women. The study showed no discrepancies in accuracy.
- A laboratory study to determine the analytical sensitivity and cut-off of the 510(k)-subject device using hCG standards of known concentration. The data demonstrate that the analytical sensitivity is 10 mIU/mL with a 50/50 cutoff of 6 mIU/mL for both midstream and dip method.
- A consumer study to demonstrate the ability of lay users to obtain similar results around the established sensitivity and cutoff as laboratory professionals. The data demonstrate similar device performance between lay users and laboratory professionals.
- A laboratory study to assess intra and inter lot precision of the 510(k)-subject device using hCG standards of known concentration. The data demonstrate no intra nor inter lot-to-lot variability.
- Laboratory studies to demonstrate that potential interfering substances and homologous hormones do not affect the performance of the 510(k)-subject device. The data demonstrate no effect on the performance of the device.
- A laboratory study to demonstrate that no high dose hook effect is observed when the 510(k)-subject is challenged with very high levels of intact hCG. The data demonstrate no effect on the performance of the device.
- A laboratory study to determine the effect of high levels of hCG βcf on device performance. The results of this study show no detrimental effect on the performance of the device.
- An early pregnancy detection study using urine samples from conceptive cycles to demonstrate that the 510(k)-subject device can detect hCG days before the missed period. The data demonstrate that the device can detect hCG 6 days before the missed period.
- A laboratory study to determine the performance of the 510(k)-subject device with urine samples quantified for hCG from pre-, peri-, and post-menopausal women. The data demonstrate that the potential for false positive results in the sub-populations is negligible.

- A consumer self-use study to determine the ability of the consumers to perform the test and interpret the results correctly. The data demonstrate that consumers can perform the test and interpret the result correctly.

Conclusion: The results of the above listed studies demonstrate that the 510(k)-subject device is substantially equivalent to the currently marketed First Response™ Early Result Pregnancy Test. The device is safe and effective for the intended use.

References:

1. McChesney R, Wilcox AJ, O'Connor JF, Weinberg CR, Baird DD, Schlatterer JP, et al. Intact hCG, free hCG beta subunit and hCG beta core fragment: longitudinal patterns in urine during early pregnancy. Hum Reprod 2005:20:928-35.

2. Gronowski A, Cervinski M, Stenman UH, Woodworth A, Ashby L, Scott MG. False-negative results in point-of-care qualitative human chorionic gonadotropin (hCG) devices due to excess hCGβ core fragment. Clin Chem 2009; 55:7; 1389-1394.

3. Kato Y, Braunstein GD. Beta-core fragment is a major form of immunoreactive urinary chorionic gonadotropin in human pregnancy. J Clin Endocrinol Metab 1988;66: 1197-201.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 26, 2013

Church and Dwight Co., Inc.
C/O Joseph Ciccone
469 North Harrison St
PRINCETON NJ 08543

Re: K123436
Trade/Device Name: FIRST RESPONSE™ Early Result Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: LCX
Dated: July 30, 2013
Received: August 8, 2013

Dear Mr. Ciccone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123436

Device Name: FIRST RESPONSE™ Early Result Pregnancy Test

Indications for Use:

The FIRST RESPONSE™ Early Result Pregnancy Test is an over-the-counter chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

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All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

Prescription Use _____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _X_ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123436